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10/662,775	09/15/2003	Andrea Marinello	930071-2001	2185

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NEW YORK, NY 10151

EXAMINER
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GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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02/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/662,775	<b>Applicant(s)</b> MARINELLO ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' response to non-final office action filed 11/23/2009.

Claims 1-33 are pending

This application contains claims 1-12 and 31-33 drawn to an invention nonelected **without** traverse in the reply filed on 10/06/2006.

Claims 13-30 are included in the prosecution.

**The following rejection has been overcome by virtue of applicants' amendment and remarks:**

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite.

**The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:**

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1611

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 13-14, 17-19, 21-26, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello (GB 2088714, IDS filed 03/15/2004), Ludwin et al. (US 2,262,711, recited in 892 form submitted 12/26/2006), and Smaldone (US 6,748,949, currently recited on 892 form).

### **Applicant Claims**

Applicants' claims 13 is directed to a device comprising a facial mask accommodated to allow unobstructed respirator<sup>7</sup> function of the nostrils and the mouth,

Art Unit: 1611

an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof. Claim 25 is directed to a method of treating sinusitis comprising the step of securing the said device to a person's head.

**Determination of the Scope and Content of the Prior Art**  
**(MPEP §2141.01)**

Marinello teaches using revulsive to treat sinusitis, wherein the preferred revulsive is mustard applied to the skin overlying the sinuses impregnated into a compress and pressed there-against by means of elastic inflatable cushion (page 5, lines 11-20). Mustard contains mustard oil, which is allyl isothiocyanate (page 3, lines 95-96). Marinello teaches impregnation of absorbent dressing (compress) with measured amount of the revulsive, applying the dressing to cutaneous surface at point overlying the inflamed organ, and exerting pressure on the dressing using inflatable elastic pad applied as near as possible to the external skin surface overlying the point of inflammation. The pressure produces the following effects: (1) squeezing the dressing and releasing the revulsive, (2) widening of the pores of the skin subjected to pressure, and (3) penetration of the revulsive through the widened pores near the inflamed area. See page 3, lines 7-55. Marinello teaches that the compression of the revulsive to the site of application allows the revulsive to enter the dilated pores of the skin and causes

Art Unit: 1611

reaction in the deep blood vessels of the body underlying the skin to which the revulsive is applied (page 2, lines 110-115). Marinello teaches avoidance of contact of the compress with the eye (page 5, lines 20-21).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Although Marinello teaches treating of sinusitis and desired avoidance of eye contact, however, Marinello does not explicitly teach the use of face mask as instantly claimed by claims 13 and 25.

Ludwin teaches medical nebulizer used for treating sinusitis (col.1, lines 1-5). The nebulizer comprises face mask, medicament in a chamber, and pressure provided to vaporize the medicine (col.1, lines 13-39). The medicaments are contained in a sponge member and applied under pressure (col.2, lines 9-12; col.3, lines 21-23). The pressure under the mask provides efficient delivery of the drugs and allows penetration of the drug into small pores of the sinus tracts (col.1, lines 36-39).

Ludwin does not explicitly teach that the face mask is unobstructive and covers the nose and mouth.

Smaldone teaches face mask for delivering pressurized drugs from nebulizer wherein the mask comprises features that reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes. The mask covers the mouth and nose and has openings (unobstructed) to release the undesired drug. The mask eliminates discomfort and potential harmful consequences that are associated

Art Unit: 1611

with masks that leak to the perinasal area and eyes. See col.5, lines 3-53; Figures 3-5, 7, 11, 13; col.7, lines 6-13, 18-22; col.15, lines 10-22. The mask having holes, therefore is unobstructive as required by claims 13 and 25, and adapted to allow respiration as required by claim 23. The face mask is made of flexible thermoplastic materials as required by claim 24 (col.7, lines 34-36). The figures show that the face mask covers the lower part of the head as required by claim 22.

**Finding of Prima Facie Obviousness Rational and Motivation**  
**(MPEP §2142-2143)**

At the time of the invention it was known to treat sinusitis by administering dressing impregnated with mustard oil to the skin overlying sinuses and using means of inflatable elastic pad to squeeze the revulsive agent from the compress to the skin as taught by Marinello. Avoidance of eye irritation was also desired.

Further, delivering medicaments to the sinuses using impregnated dressing and face mask using pressure force was known in the art at the time of the invention as taught by Ludwin.

Additionally, at the time of the invention it was known to use nebulizer to deliver drugs under pressure using masks that cover the nose and mouth that have openings to release the pressure to avoid eye irritation as taught by Smaldone.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the

Art Unit: 1611

skin overlying the inflamed sinuses as taught by Marinello, and further use a face mask to cover the impregnated compress as taught by Ludwin. One would have been motivated to do so because Ludwin teaches that sinuses can be treated using face mask and applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drug into small pores of the sinus tracts. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask to help penetration of the drug into the pores of sinus tracts to ensure efficient drug delivery to the sinuses.

Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to replace the mask taught by Ludwin with the mask that covers the nose and mouth and has openings as taught by Smaldone. One would have been motivated to do so because Smaldone teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask covering the mouth and the nose and having holes wherein the mask is comfortable and eliminates irritation of the eye.



Regarding claim 21 that recites wherein the mask covers an upper part of the face, applicants failed to show unexpected results obtained if the mask cover the upper part of the head.

Regarding claim 19 that recites using rubber pump to inflate the inflatable pad, the prior art recognized applying pressure to deliver mustard from the impregnated compress. Applicants failed to show unexpected results obtained from using the rubber pump to provide pressure over the means used by the prior art to create pressure.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 15, 16, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the article by Depree et al. (Flavour pharmaceutical properties of the volatile sulphur compounds of Wasabi), currently provided.

The combined teachings of Marinello with Ludwin and Smaldone are previously discussed as set forth in this office action.

Although Marinello teaches solution of the mustard oil, page 3, line 28, however, the reference does not explicitly teach water and its temperature to activate the revulsive agent as instantly claimed by claims 15, 16, 27 and 28.

Depree teaches that isothiocyanates that is present in mustard oil have the property of decomposition in water and their decomposition in water is temperature dependent; it is more rapidly at 37° C than at 0° C (page 333, left column, first paragraph).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard oil solution impregnated into a compress and use an inflatable elastic cushion and pressurized face mask covering the mouth and the nose and having holes as taught by the combined teachings of Marinello with Ludwin and Smaldone, and further use solution of mustard in water at a temperature between 37° C and above 0° C as taught by Depree. One would have been motivated to do so because Depree teaches that isothiocyanates that is present in mustard have the property of decomposition in water and their decomposition in water is temperature dependent, and decomposition occurs more rapidly at 37° C than at 0° C. One would reasonably expect to treat sinusitis using mustard oil solution in water impregnated into a compress and using an inflatable elastic cushion and pressurized face mask wherein the mustard is provided in water at a temperature between 37° C and above 0° C to ensure solubility of the active agent in the solution.

Therefore, the temperature currently claimed falls within that known and taught by the prior art. It has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

**See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the Bracken (US 5,429,126, current 892 form).

The combined teachings of Marinello with Ludwin and Smaldone are previously discussed as set forth in this office action.

Although Ludwin and Smaldone teach face masks, however, the references do not explicitly teach means for securing the mask to the head as instantly claimed by claims 20 and 29.

Bracken teaches respiratory mask that is secure, comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a person to attach and remove the respiratory mask with ease and to remove and reinsert the elastic strap repeatedly without constant damage and frequent replacement (col.1, lines 53-60; figures).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard oil solution impregnated into a compress and using an inflatable elastic cushion and pressurized face mask covering the mouth and the nose and having holes as taught by the combined teachings of

Art Unit: 1611

Marinello with Ludwin and Smaldone, and further use mask having elastic strips to secure the mask of the head of user as taught by Bracken. One would have been motivated to do so because Bracken teaches that such a mask with elastic strips is secure, comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a person to attach and remove the respiratory mask with ease and to remove and reinsert the elastic strap repeatedly without constant damage and frequent replacement. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion and pressurized face mask having securing elastic strips to secure the mask to the user head wherein the mask is secure, comfortable, snug fit to the user's head and further permits mobility and repeated use of the mask.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

7. Applicant's arguments filed 11/23/2009 have been fully considered but they are not persuasive.

Applicants argue that Marinello is directed to use oil of mustard dissolved in vegetable oil, the vegetable oil producing the unexpected result of attenuating the revulsive power of the oil. The revulsive and vegetable oil mixture when applied reaches

Art Unit: 1611

the blood vessels and increase the blood flow. The vegetable oil, because of its characteristic density is not suitable to penetrate the skin pores to reach the bones and mucous membranes underlying the skin. Marinello teaches the advantage of hyperemia and slow general tumefaction in the area. Both of these conditions are related to increased blood flow. There is no suggestion that the composition or method of Marinello is suitable for absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person as required by claim 13.

In response to this argument, it is argued that the present claims' language does not exclude the presence of vegetable oils. Case 4, page 5, lines 11-20 taught by Marinello is directed to using revulsive to treat sinusitis, The reference teaches the preferred revulsive is **mustard** applied to the skin overlying the sinuses **impregnated into a compress and pressed there-against by means of elastic inflatable cushion** (page 5, lines 11-20). The reference further teaches in page 5, lines 27-31, that "the present invention achieves therapeutic results in a variety of situations, where increased blood flow to an internal inflammation, injury or disthesis is necessary." Therefore, the reference teaches absorption of mustard oil to the internal organs to provide therapeutic effect, and teaches treating sinusitis. **Applicants disclosed in page 8, lines 10-13 that "A portion of the medication is dispersed in the blood stream and a portion reaches the vessels feeding the injured area, thus provoking enlargement, greater supply of blood and consequent treatment effects."** Therefore, the reference teaches the same mechanism by which the mustard oil reaches the sinuses as disclosed by applicants. Absorbed mustard oil to the blood stream will be delivered to

Art Unit: 1611

the surrounding tissues including sinuses. In particular the reference teaches treating sinuses and delivering the mustard oils to sinuses under the site of application. Once the mustard cross the skin barrier, it is inevitable to prevent its access to the blood stream. Blood vessels are every where in the body including cutaneous tissue.

Therefore the elements of the present claims are taught by the reference, and delivery through blood stream is within the scope of the present invention. Burden is on applicants to show that the mustard oil when combined with vegetable oils will not provide treatment of sinusitis.

Applicants argue that Ludwin is directed to a nebulizer, which vaporizes medicaments to be applied in the form of a vapor into respiratory passages. The application of medicament to the small pores of the tracts of the sinus tracts through vaporization as taught by Ludwin is not the same as applying an active ingredient through the skin to underlying bone. The reference does not teach an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or compress having an active, or a device that promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes as required by claim 13.

In response to this argument, it is argued that Ludwin is relied upon for teaching structure of the mask comprising impregnated dressing in combination with face mask. Ludwin further teaches that applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drug into small pores of the sinus

Art Unit: 1611

tracts. Therefore, Ludwin is relied upon for teaching the structure of face mask and pressure under the face mask. Delivery of revulsive from skin to the sinuses is already taught by Marinello. One cannot attack the references individually when obviousness is based on combination of the references.

Applicants argue that Smaldone is directed to a face mask for a nebulizer, the reference contains the same deficiencies as discussed above for Ludwin. The mask taught by Smaldone does not provide for unobstructed respiration because the reference teaches that in order for the inhalation of the patient to create a negative pressure within the mask reservoir, some resistance to the inhalation must be created.

In response to this argument, it is argued that Smaldone is relied upon for teaching structure of the mask that covers the nose and mouth and has openings. The reference teaches the mask is adapted to allow respiration as required by claim 23. The face mask is made of flexible thermoplastic materials as required by claim 24 (col.7, lines 34-36). The figures show that the face mask covers the lower part of the head as required by claim 22. Smaldone further teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. Applicants also desired to protect the eye. Delivery of revulsive from skin to the sinuses is already taught by Marinello. One cannot attack the references individually when obviousness is based on combination of the references.

Applicants argue that a prima facie case has not been made, for at least the following reasons. Marinello discloses use of revulsive and vegetable oil composition to stimulate blood flow in tissue underlying the skin. There is no disclosure that the active ingredients are capable of penetration through the skin to bones underlying mucous membranes in a sinus as claimed. Applicants argue that the Office Action misconstrues the teaching of the Ludwin that teaches nebulizer provides the active ingredient in aerosol form through the nasal cavity. Marinello to include the mask of Ludwin would change the principle of operation of Marinello, the Office Action has failed to make a prima facie case of obviousness. Modifying Marinello with the nebulizer mask of Smaldone is not prima facie obvious for the same reasons as discussed with regard to Ludwin.

In response to this argument, it is argued that, as set forth in this office action, Marinello teaches using revulsive to treat sinusitis, and teaches that “the present invention achieves therapeutic results in a variety of situations, where increased blood flow to an internal inflammation, injury or disthesis is necessary.” Therefore, the reference teaches absorption of mustard oil to the internal organs to provide therapeutic effect, and teaches treating sinusitis. Applicants disclosed in page 8, lines 10-13 that “A portion of the medication is dispersed in the blood stream and a portion reaches the vessels feeding the injured area, thus provoking enlargement, greater supply of blood and consequent treatment effects.” Therefore, the reference teaches the same mechanism by which the mustard oil reaches the sinuses as disclosed by applicants.



Art Unit: 1611

Absorbed mustard oil to the blood stream will be delivered to the surrounding tissues including sinuses. In particular, the reference teaches treating sinuses and delivering the mustard oils to sinuses under the site of application. Ludwin is relied upon for teaching of delivery of medicaments to the sinuses using impregnated dressing combined with face mask using pressure force. Ludwin further teaches that applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drug into small pores of the sinus tracts. Smaldone is relied upon for teaching mask that covers the nose and mouth and has openings. Smaldone further teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses as taught by Marinello, and further use a face mask to cover the impregnated compress as taught by Ludwin. One would have been motivated to do so because Ludwin teaches that sinuses can be treated using face mask and applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drug into small pores of the sinus tracts. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin

Art Unit: 1611

overlying the inflamed sinuses, and further use pressurized face mask to help penetration of the drug into the pores of sinus tracts to ensure efficient drug delivery to the sinuses. Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to replace the mask taught by Ludwin with the mask that covers the nose and mouth and has openings as taught by Smaldone. One would have been motivated to do so because Smaldone teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask covering the mouth and the nose and having holes wherein the mask is comfortable and eliminates irritation of the eye.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine

Art Unit: 1611

the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR

INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicants argue that independent claim 25 is similar or somewhat similar in scope to revised independent claim 13 and is therefore allowable for similar or somewhat similar reasons to those for claim 13. Further, claims 14-24, which depend from claim 13, and claims 26-30 which depend from claim 25, are allowable as well.

In response to this argument, for the reasons set forth in this office action claims 13 in not allowable, and similarly claim 25 and claims 14-24 and 26-30 that depend from claims 13 and 25, respectively.

Applicants argue that The Examiner has made of record, but not applied, several documents. The Applicants appreciate the Examiner's implicit finding that these documents, whether considered alone or in combination with others, do not render the claims of the present application unpatentable.

In response to this argument, the examiner did not make any reference of record without applying them for claims rejection. Claims 15, 16, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the article by Depree et al. (Flavour pharmaceutical properties of the volatile sulphur compounds of Wasabi). Claims 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the Bracken (US 5,429,126). The rejections are maintained for reasons of record.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1611

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1611

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/  
Primary Examiner, Art Unit 1611